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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,168	08/25/2005	Helen Francis-Lang	EX03-065C-US	3479

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/528,168	FRANCIS-LANG ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 1-25 are pending in the application and are currently under prosecution.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13: Group 1, claims 1-in-part, 4, 5, drawn to a cell free method of identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a small molecule.

Group 2, claims 1-in-part, 5, 7,drawn to a cell free method of identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antibody.

Group 3, claims 1-in-part, 2-5, 6-in-part, drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a small

molecule

Group 4, claims 1-in-part, 2-3, 5, 6-in-part ,7,drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antibody.

Group 5, claims 1-in-part, 2-5, 6-in-part, drawn to a method of identifying a candidate p21 modulating agent comprising an cell proliferation assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a small molecule

Group 6, claims 1-in-part, 2-3, 5, 6-in-part, 7,drawn to a method of identifying a candidate p21 modulating agent comprising an cell proliferation assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a

candidate p21 pathway modulating agent, wherein the test agent is an antibody.

Group 7, claims 1-in-part, 2-5, 6-in-part, drawn to a method of identifying a candidate p21 modulating agent comprising an angiogenesis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a small molecule

Group 8, claims 1-in-part, 2-3, 5, 6-in-part, 7,drawn to a method of identifying a candidate p21 modulating agent comprising an angiogenesis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antibody.

Group 9, claims 1-in-part, 2-5, 6-in-part, drawn to a method of identifying a candidate p21 modulating agent comprising hypoxic induction assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a

candidate p21 pathway modulating agent, wherein the test agent is a small molecule

Group 10, claims 1-in-part, 2-3, 5, 6-in-part , 7 drawn to a method of identifying a candidate p21 modulating agent comprising a hypoxic induction assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antibody.

Group 11, claims 1-in-part, 9, drawn to a cell free method of identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 12, claims 1-in-part, 10, drawn to a cell free method of identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 13, claims 1-in-part , 2-3, 6-in-part, 9, drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 14, claims 1-in-part , 2-3, 6-in-part, 10, drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 15, claims 1-in-part , 2-3, 6-in-part, 9, drawn to a method of identifying a candidate p21 modulating agent comprising an angiogenesis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 16, claims 1-in-part , 2-3, 6-in-part, 10, drawn to a method of identifying a candidate p21 modulating agent comprising an angiogenesis assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 17, claims 1-in-part , 2-3, 6-in-part, 9, drawn to a method of identifying a candidate p21 modulating agent comprising a cell proliferation assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 18, claims 1-in-part , 2-3, 6-in-part,10, drawn to a method of identifying a candidate p21 modulating agent comprising a cell proliferation assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 19, claims 1-in-part , 2-3, 6-in-part, 9, drawn to a method of identifying a candidate p21 modulating agent comprising an hypoxic induction assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 20, claims 1-in-part , 2-3, 6-in-part, 10, drawn to a method of identifying a candidate p21 modulating agent comprising an hypoxic induction assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 21, claims 1-in-part , 2-3, 6-in-part, 9, drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense

oligomer.

Group 22, claims 1-in-part , 2-3, 6-in-part, 10, drawn to a method of identifying a candidate p21 modulating agent comprising an apoptosis assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 23, claims 1-in-part , 2-3, 8-9, drawn to a method of identifying a candidate p21 modulating agent comprising an expression assay system for identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 nucleic acid, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is an antisense oligomer.

Group 24, claims 1-in-part , 2-3, 8, 10, drawn to a method of identifying a candidate p21 modulating agent comprising an expression assay system identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a PMO.

Group 25, claims 1-in-part, 11, 16-in-part, 17, 20-in-part drawn to an in vitro method of identifying a polypeptide candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 26 claims 1-in-part, 11, 16-in-part, 17, 20-in-part drawn to an in vitro method of identifying a small molecule candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 27 claims 1-in-part, 11, 16-in-part, 17, 20-in-part drawn to an in vitro method of identifying a nucleic acid candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 28, claims 1-in-part, 11, 12, 16-in-part, 18-19, 20-in-part drawn to an in vivo method of identifying a polypeptide candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 29 claims 1-in-part, 11, 12, 16-in-part, 18-19, 20-in-part drawn to an in vivo method of identifying a small molecule candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 30 claims 1-in-part, 11, 12, 16-in-part, 18-19, 20-in-part drawn to an in vivo method of identifying a nucleic acid candidate modulator of p21 pathway as contemplated in the specification and administering said candidate to a model system and detecting a phenotypic change in the model system that indicates that the p21 function is restored.

Group 31, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a FLJ20647 polypeptide wherein the agent is a small molecule modulator.

Group 32, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a FLJ20647 polypeptide wherein the agent is an antibody.

Group 33, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a

FLJ20647 polypeptide wherein the agent is a nucleic acid modulator.

Group 34, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a FLJ20647 nucleic acid wherein the agent is a small molecule modulator.

Group 35, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a FLJ20647 nucleic acid wherein the agent is an antibody.

Group 36, claims 20-in-part, 21, 22-in-part drawn to method of modulating p21 pathway in a mammal predetermined to have a pathology associated with the p21 pathway comprising contacting a cell with an agent that specifically binds to a FLJ20647 nucleic acid wherein the agent is a nucleic acid modulator.

Group 37, claims 23-25, drawn to a method for diagnosing a disease in a patient comprising contacting a biological sample from the patient with a probe for FLJ20647 nucleic acid expression as contemplated in the specification.

Group 38, claims 23-25, drawn to a method for diagnosing a disease in a patient comprising contacting a biological sample from the patient with a probe for FLJ20647 polypeptide expression as contemplated in the specification.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group I, forms a single general inventive concept comprising a cell free method of identifying a candidate p21 pathway modulating agent comprising providing the assay system comprising a FLJ20647 polypeptide, contacting the system with a test agent, detecting a test agent-biased activity, wherein a difference between the test agent-biased activity and the reference activity identifies the test agent as a candidate p21 pathway modulating agent, wherein the test agent is a small molecule.

Groups 2-38 are methods clearly different from that of Group. Given that the claims are all drawn to methods different from that of Group 1, the additional claimed methods do not meet the requirement for categories considered to have unity of invention.

For these reasons the claimed inventions are not so linked as to form a single general inventive concept and all methods are properly broken out as separate groups.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

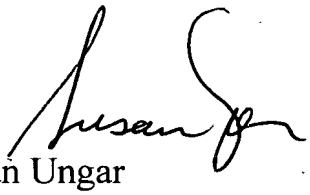
6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898.. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan Ungar
Primary Patent Examiner
August 30, 2007